packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(f)(1)—the label of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Quad capsules. 502(b)(1)—when shipped, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Thyroid tablets. 502(b)—while held for sale, the article failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of contents; 502(e)(1)—the label of the article failed to bear the common or usual name of the article; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its labeling failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (3-btl. lot). 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning—may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Amobarbital sodium capsules (15-btl., and 1 btl. lots). 502(b)(1)—while held for sale, the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(d)—when shipped, the article contained a quantity of amobarbital, a habit forming derivative of barbituric acid, and its label failed to bear in juxtaposition with the statement of the quantity of such derivative in the article the statement "Warning-may be habit forming"; 502(f)(1)—the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was a drug subject to 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that a number of vitamin and mineral tablets were misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: 1-16-59. Default—the vitamin and mineral capsules were delivered to a charitable institution for its use and not for sale, and the other articles were destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

5650. Douche powder. (F.D.C. No. 41427. S. No. 41-182 P.)

QUANTITY: 94 5-oz. jars and 34 12-oz. jars at Seattle, Wash.

*See also No. 5649.

SHIPPED: 1-20-58, from Los Angeles, Calif., by Takara Laboratories Corp.

LABEL IN PART: "Takara Douche Powder * * * Alum, Oil Peppermint, Boric Acid, Phenol * * * For a Douche: Dissolve one teaspoonful of Takara to each quart of comfortably warm water. Use as desired."

LIBELED: 2-14-58, W. Dist. Wash.

CHARGE: 502(f)(2)—the labeling of the article, when shipped, failed to bear such adequate warnings against unsafe dosage or duration of administration in such manner and form as are necessary for the protection of users, since its labeling failed to warn that the article should not be used more than twice weekly, unless otherwise directed by a physician.

DISPOSITION: 7-9-58. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS AND DEVICES FOR HUMAN USE*

5651. Pentosol. (F.D.C. No. 40611. S. Nos. 25-669 M, 66-340 M, 74-129 M.)

INFORMATION FILED: 3-24-58, N. Dist. Calif., against Invenex Pharmaceuticals, a corporation, San Francisco, Calif., and Jack R. Baker, president.

ALLEGED VIOLATION: On 6-10-57, the defendants gave to a firm engaged in the business of shipping drugs in interstate commerce, including *Pentosol* supplied by the defendants, an invoice containing a guaranty that the *Pentosol* listed in the invoice was neither adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

On 6-10-57, the defendants sold, invoiced, and delivered, a quantity of *Pentosol* to the holder of the guaranty at Oakland, Calif.

LABEL IN PART: (Vial) "Pentosol 100cc Multiple Dose Vial Sterile Solution Each cc Contains: Pentobarbital Sodium 1 gr Benzyl Alcohol 2% Water for Injection qs."

CHARGE: 501(c)—the strength of the article differed from that which it purported and was represented to possess, namely, 1 grain of pentobarbital sodium in each cubic centimeter; and 502(a)—the label statement "Each cc Contains: Pentobarbital Sodium 1 gr." was false and misleading since each cubic centimeter of the article contained less than 1 gr. of pentobarbital sodium.

PLEA: Nolo contendere.

DISPOSITION: 8-12-58. Corporation—fined $200; individual—fined $50.

5652. Sodium nitrite and phenobarbital tablets. (F.D.C. No. 41435. S. No. 14-761 P.)

QUANTITY: 3 500-tablet pkgs., 8 100-tablet pkgs., and 21 2,500-tablet pkgs., at Muncie, Ind.

SHIPPED: 10-18-57, from Cincinnati, Ohio.

RESULTS OF INVESTIGATION: Examination showed the article to be a green-colored tablet containing about 0.23 grain of phenobarbital per tablet, or approximately the declared amount, and about 1.38 grains of sodium nitrite per tablet, or about 69 percent of the declared amount.

The article had been repackaged by the consignee from bulk stock shipped as described above.

LIBELED: 3-6-58, S. Dist. Ind.

*See also Nos. 5641, 5642.